K024291

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PREMARKET NOTIFICATION
SUMMARY OF SUBTANTIAL EQUIVALENCE
Arthrex Continuous Wave III Arthroscopy Pump

NAME OF SPONSOR:

Arthrex, Inc.
2885 S. Horseshoe Drive
Naples, Florida 34104

510(K) CONTACT:

Sally Foust, RAC
Regulatory Affairs Specialist
Arthrex, Inc.
Telephone: (239) 643-5553 ext. 1251
FAX: (239) 430-3494
E-mail: sfoust@arthrex.com

TRADE NAME:

Arthrex Continuous Wave III Arthroscopy Pump

COMMON NAME:

Pump

CLASSIFICATION:

Arthroscope
21 CFR 888.1111

DEVICE PRODUCT CODE: HRX

DEVICE DESCRIPTION AND INTENDED USE:
The Arthrex Continuous Wave III Arthroscopy Pump is a roller, peristaltic, arthroscopic pump designed with a universal input grade switching power supply allowing the pump to function automatically within voltages ranges found in Europe and in the Americas. The pump is designed with upgraded software, employs a combination vacuum fluorescent and dot matrix display for high visibility, uses membrane type switch overlays for user inputs, and has an added flush function.

The Arthrex Continuous Wave III Arthroscopy Pump is intended to provide consistent, non-pulsing control of intra-articular irrigation and distention pressuring during all phases of arthroscopic surgery.

SUBSTANTIAL EQUIVALENCE
The Arthrex Continuous Wave III Arthroscopic Pump is a functional equivalent of the currently marketed AR-6400 and the discontinued AR-6300 Arthrex arthroscopic pumps. The subject pump retains current functions and interfaces and is determined by Arthrex, Inc. to be substantially equivalent to its Arthrex pump predecessors and other currently marketed predicate devices.

The addition of a universal input grade switching power supply, of an improved visual display, of an autoclavable remote, and of an upgrade software package does not affect the safety and effectiveness of the subject device when compared to its Arthrex pump predecessors and other predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2003

Ms. Sally Foust, RAC
Regulatory Affairs Specialist
Arthrex, Inc.
2885 South Horseshoe Drive
Naples, Florida 34104

Re: K024291
Trade/Device Name: Arthrex Continuous Wave III Arthroscopy Pump
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope and accessories
Regulatory Class: II
Product Code: HRX
Dated: December 20, 2002
Received: December 24, 2002

Dear Ms. Foust:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K024291

INDICATIONS FOR USE:

The Arthrex Continuous Wave III Arthroscopy Pump is intended to provide consistent, non-pulsing control of intra-articular irrigation and distention pressuring during all phases of arthroscopic surgery.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)

for Mark N Milhous

Division Sign-Off
Division of General, Restorative
and Neurological Devices

510(k) Number K024291